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GROUP ART UNIT 1208

PAPER NUMBER 3

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COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ___ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-19 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-19 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

15. Claims 1-19 are in the case.

16. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-2, 4-19 are rejected under 35 U.S.C. § 103 as being unpatentable over Cantrell et al. US. 5,250,542 (cited on 1449) in view of Berge et al.

Cantrell disclose applicants' claimed compounds and intermediates and their pharmaceutically acceptable salts (see generic disclosure col. 2-3 and examples 4, 12 and 13 corresponding to applicants' claims 1, 11 and 4).

The difference between applicants' claims and Cantrell's teaching is that the specific pharmaceutically acceptable salts and purer form of such known salts are particularly named.

The purer/ crystalline form, resulted from purification of a known product as a mere change in degree in its properties, is not patentable. Cf. Ex parte Windhaus 15 USPQ 45; In re Ridgeway 25 USPQ 202; In re Merz 38 USPQ 143; In re Macallum 41 USPQ 146; In re King 43 USPQ 400 Ex parte Sparhawk 64 USPQ 339; In re Weijlard et al. 69 USPQ 86; In re Johnson et al. 37 USPQ 75, Ex parte Cavillito 89 USPQ 449, Ex parte Snell 86 USPQ 496; In re Fisher 135 USPQ 22, Ex parte Hartop 139 USPQ 525; Ex parte Siddiqui 156 USPQ 426. Changing the form, purity or other characteristic of an old product does not render the novel form patentable where the difference in form, purity of characteristic was rendered obvious by the prior art. In re Cofer (CCPA 1966) 354 F2d 664, 148 USPQ 268.

One having ordinary skill in the art would have found the claimed compounds prima facie obvious because they are generically embraced by the Cantrell reference with enabling teaching exemplified by dibenzoic tartaric acid (Col. 13, lines 32-36) and hydrochloric acid salts (col.15, lines 17-23 and HCl salts among the examples). It is well settled patent law that a reference may be relied upon for all that it would have reasonably conveyed to one having ordinary skill in the art. In re Fracalossi 215 USPQ 569; In re Lamberti 192 USPQ 278; In re Rinehardt 189 USPQ 143; In re Susi 169 USPQ 423. These generic teaching of pharmaceutically acceptable salts (see claim 1)

coupled with the exemplified enabling disclosure and the conventional acceptable pharmaceutical salts (Berge p.2 Table 1) available to an artisan having ordinary skill, would have rendered applicants' claimed invention prima facie obvious.

17. Claim 3 is rejected under 35 U.S.C. § 103 as being unpatentable over Cantrell et al in view of Cheronis.

Cantrell et al disclosed processes of making applicants' products and intermediates. A recrystallization process of an intermediate from alcohol is seen at col.16 lines 10-14.

The difference between applicants' process and Cantrell's teaching is that a different species of Cantrell's compounds is recrystallized from a methanol/H_2O system.

Cheronis taught that crystallization is a conventional textbook taught method in purification of chemicals and choices of a suitable solvent is conventional skill in the chemical art, (see p.31-33).

An artisan having ordinary skill would be motivated to conduct the claimed process because it was taught by Cantrell that (i) it is desirable to purify the product (see col.14-15, purify by chromatography) and (ii) some intermediates have been successfully purified by recrystallization. Therefore, it is prima facie obvious for an artisan to choose crystallization with the conventional textbook taught skill of choosing a suitable solvent which is the claimed invention.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Chang whose telephone number is (703) 308-4702.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

A facsimile center has been established in Group 1200, room 3C10. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine is (703) 308-4556 or 305-3592.

CHANG:tcj
May 16, 1994

CELIA CHANG
PATENT EXAMINER
GROUP 1200